MAR - 1 2001

K010511

0-000019

Attachment 4

Summary of Safety and Effectiveness

Submitter's Name/Contact Person

The submitter of this special 510(k) is:

Cordis Neurovascular, Inc.
14000 N.W. 57th Court
Miami Lakes, Florida 33014

Establishment Registration No. 1058196

Contact: Amarilys Machado
Regulatory Affairs Associate II

Tel: (305) 512-6493
Fax: (305) 512-6520

February 13, 2001

Trade Name / Common Name

Trade Name: AGILITY™ Steerable Guidewire
Common/Classification Name: Catheter Guidewire

Classification

Class II

Performance Standards

The FDA under section 514 of the Food, Drug and Cosmetic Act has not established performance standards.

Intended Use

The AGILITY™ 0.016 inch Soft and Standard Steerable Guidewires are intended for selective placement of microcatheters and other devices in the neuro and peripheral vasculature.

Device Description

The hydrophilically coated AGILITY™ 0.016 Guidewires consist of a stainless steel wire core and a radiopaque platinum/tungsten coil on the distal tip.

The basic principle of the guidewires is to act as a monorail that catheters can track over to reach a particular area of the neuro and peripheral vasculature. They have a nominal outside diameter of 0.016 inch and nominal overall length of up to 350cm.

Continued on next page

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2001

Ms. Amarilys Machado
Regulatory Affairs Associate II
Cordis Neurovascular, Inc
14000 N.W. 57th Court
Maimi, FL 33014

Re: K010511
Trade Name: AGILITY™ Steerable Guidewireatheter
Regulatory Class: II (two)
Product Code: 74 DQX
Dated: February 13, 2001
Received: February 21, 2001

Dear Ms. Machado:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): The 510(k) number has not yet been assigned.

Device Name: AGILITY™ Steerable Guidewires.

Indications for Use Statement

The AGILITY™ Steerable Guidewires are intended for selective placement of microcatheters and other devices in the neuro and peripheral vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

2/28/11

Division of Cardiovascular & Respiratory Devices
510(k) Number K010511